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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,454	12/05/2006	Riccardo Bertini	6274-0122PUS1	5756
2292 7590 03/22/2012 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER STONE, CHRISTOPHER R				
ART UNIT 1628		PAPER NUMBER		
NOTIFICATION DATE 03/22/2012		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary**Application No.**

10/588,454

Applicant(s)

BERTINI ET AL.

Examiner

CHRISTOPHER R. STONE

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 5-14 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 5-14 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Applicants' arguments, filed November 17, 2011, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 5-14 are pending and under examination. The compound of formula II (claim 10) is the elected specie of compound of formula I currently under examination.

Rejections Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobinick (US 2001/0016195 A1, cited on the IDS filed December 5, 2006) in view of Bertini et al (EP 1123276 B1, provided by Applicant).

Claims 5-14 are drawn to a method of treating spinal cord injury consisting of administering the compound of formula II.

Tobinick teaches that antagonists of interleukin-8 (IL-8) are useful in the treatment of spinal cord injury (abstract). Tobinick does not teach the compound of formula II as a particular IL-8 antagonist or the regimen specified by claims 11-13. Bertini et al (EP 1123276 B1, provided by Applicant) teaches that the compound of formula II is an IL-8 antagonist (p. 14, lines 12-27, useful in the treatment of IL-8 mediated pathologies when administered intravenously or intramuscularly, as a bolus, at a daily dosage of from 1 to 1500mg (p. 16, line 23 to p. 17, line 17). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to practice the practice a method consisting of administering the compound of formula II intravenously or intramuscularly, as a bolus, at a daily dosage of from 1 to 1500mg to a patient with a spinal cord injury, since this regimen was known to inhibit IL-8 and IL-8 inhibitors were known to be useful in the treatment of spinal cord injury, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success. Tobinick and Bertini et al do not expressly teach

that said method blocks oligodendrocyte apoptosis, reduces tissue damage or promotes recovery following a spinal cord injury; however this language merely states the intended purpose of an active step positively recited, i.e. the administration of the elected specie of compound to a patient with a spinal cord injury, and thus said language is non-limiting. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims, see *Bristol-Myers Squibb Company v. Ben Venue Laboratories* 58 USPQ2d 1508 (CAFC 2001). In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

Response to Arguments

Applicant continues to argue that, contrary to the teachings of Tobinick, one of ordinary skill in the art would not have been motivated to use an IL-8 antagonist as the sole active agent in the treatment of spinal cord injury, given that other cytokines

involved in the inflammatory process were identified as targets for the treatment of spinal cord injury.

Applicant's arguments have been fully considered, but are not found to be persuasive for reasons of record, summarized below.

The prior art as a whole has been carefully considered and IL-8 is recognized as a proinflammatory cytokine (a chemokine that attracts inflammatory cells in particular) and a molecular target for the treatment of SCI, regardless of other disclosed targets for the treatment of disease. While the art suggests other molecular targets for the treatment of SCI (e.g. TNF-alpha, IL-1, ICAM1), it does not discredit the use IL-8 antagonists in the treatment of the condition (see e.g. Tonai et al, cited below). In fact, Tobinick et al expressly teaches the administration of an IL-8 antagonist for the treatment of SCI and provides a mechanism by which the compounds act to treat the condition, e.g. anti-inflammatory and neuroprotective activity that ameliorates edema and provides dosing and administration information allowing one of ordinary skill in the art to practice the method with a reasonable expectation of success, regardless of a lack of disclosed examples using an IL-8 antagonist (see e.g. paragraphs 0067-0068 and claims 24, 25 and 28). Additionally, as noted in the previous Office Action, Tonai et al, Journal of Neurochemistry, Vol. 78, p. 1064-1072, 2001, p. 1064, last paragraph through p. 1065, second paragraph, provides further evidence that the prior art as a whole recognized IL-8 as a proinflammatory cytokine and a target for the treatment of SCI at the time of the instantly claimed invention, as taught by the applied reference Tobinick et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Brandon J Fetterolf/

Application/Control Number: 10/588,454

Page 7

Art Unit: 1628

Supervisory Patent Examiner, Art Unit 1628